

Docket No. CRD5071USANP

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert Falotico, et al.

Serial No.: 10/805,736

Art Unit: 3763

Filed

: March 22, 2004

Examiner:

For

: LOCAL VASCULAR DELIVERY OF PANZEM® IN COMBINATION WITH RAPAMYCIN TO PREVENT RESTENOSIS FOLLOWING

VASCULAR INJURY

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, F.O. Box 1450, Alexandria, VA 22313-1450 on

November 14, 2005
(Date of Deposit)
Carl J. Evens (Name of applicant, assignee, or Registered Representative
/Carl J. Evens/
(Signature)
November 14, 2005
(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under \$1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under \$1.114, no additional fee is required.

	dance wren b	11123 (4) /			
Disclosure Stateme	nt is being	filed in co	nnection	with [] the
first or [second	After Final S	Submission,	therefor	ce:	
☐ Sta	atement in Ac	cordance wi	ith §1.97	(e)	
(at	ttached); or				
☐ Ple	ease charge D	eposit Acco	ount No.	10-	
07	50/ /	the fee of	\$180.00	as set	forth
in	\$1.17(p).				

In accordance with \$1 129(a), this Information

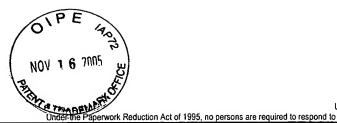
In accordance with \$1.97(c), this Information
Disclosure Statement is being filed after the period set forth
in \$1.97(b) above but before the mailing date of either a Final
Action under \$1.113 or a Notice of Allowance under \$1.311, or
an action that otherwise closes prosecution and that it is
accompanied by one of:

			Statement in Accordance with \$1.97(e)
			(attached); or
			Please charge Deposit Account No. 10-
			0750/ / the fee of $$180.00$ as set forth
			in \$1.17(p).
		In a	ccordance with \$1.97(d), this Information
	Disclosure	Stat	tement is being filed after the mailing date of
	either a E	inal	Action under §1.113 or a Notice of Allowance
,	under §1.	311 k	out before the payment of the Issue Fee.
			ereby petition(s) for consideration of this
			sclosure Statement. Included are: Statement in
	Accordance	with	n \$1.97(e) as set forth below and the fee of
			forth in \$1.17(p).
	П	Copi	es of each of the references listed on the
	attached F	-	PTO-1449 are enclosed herewith.
•	accaemea i	OLIN A	
		Copi	es of references listed on the attached Form PTO
	1449 are e	enclos	sed herewith EXCEPT THAT:
			In view of the voluminous nature of references
	•		[list as appropriate], and the likelihood that
			these references are available to the Examiner,
			copies are not enclosed herewith.
		П	If any of the foregoing publications are not
			available to the Examiner, Applicant will
			endeavor to supply copies at the Examiner's
			request.
	\boxtimes	Copi	es of only foreign patent documents and non-
	patent lit	erati	are are enclosed in accordance with 37 CFR 1.98
	(a)(2).		•

∑ There are no listed references which are not in the
English language.
The relevance of those listed references which are not in the English language is as follows:
Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
Please charge any deficiency or credit any overpayment to
Deposit Account No. 10-0750/CRD5071USANP/CJE. This form is
submitted in triplicate.
Respectfully submitted,
/Carl J. Evens/
Carl J. Evens Reg. No. 33,874 Attorney for Applicants
Johnson & Johnson

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2518

DATED: November 14, 2005



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 4

valid OMB control number.
10/805,736
March 22, 2004
Robert Falotico
3763
CRD5071USANP

		Sneet	. 51 -1	U.S. PATENT DOCUMENTS		
		U.S. Patent Docum	nent			
Examiner Initials	Cite No. ¹	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages of relevant figures appear
		3,929,992		Sehgal et al.	12/30/1975	
<u></u>		3,959,078		Guire et al.	05/25/1976	
		4,350,160		Kolesov et al.	09/21/1982	
		4,366,819		Kaster	01/4/1983	
		4,368,736		Kaster	01/18/1983	
		4,624,257		Berggren et al.	11/25/1986	
		4,722,906		Guire et al.	02/02/1988	
		4,733,665		Palmaz	03/29/1988	
		4,739,762		Palmaz	04/26/1988	
		4,776,337		Palmaz	10/11/1988	·
		4,917,090		Berggren et al.	04/17/1990	
		4,917,091		Berggren et al.	04/17/1990	
-		5,229,172		Cahalan et al.	07/20/1993	
		5,234,447		Kaster et al.	08/10/1993	
		5,308,641		Cahalan et al.	05/03/1994	
		5,350,800		Cahalan et al.	09/27/1994	
		5,415,938		Cahalan et al.	05/16/1995	
		5,837,313		Ding et al.	11/17/1998	
		6,099,562		Ding et al.	08/08/2000	
		6,120,536		Ding et al.	09/19/2000	
		6,153,252		Hossainy et al.	11/28/2000	
		6,425,898	B1	Wilson et al.	07/30/2002	

- [Examiner	Date	
- 1	Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0551-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 2 of 4

a collection of information unless it displays a	a valid Civid control flustact.
Application Number	10/805,736
Filing Date	March 22, 2004
First Named Inventor	Robert Falotico
Group Art Unit	3763
Examiner Name	
Attorney Docket Number	CRD5071USANP

FOREIGN PATENT DOCUMENTS

		Foreign	Patent Docu	ment	Name of Patentee or	Date of Publication of Cited Document	Pages, Columns, Lines, where relevant	
Examiner Initials	Cite No. ¹	Office ³	Number⁴	KindCode ⁵	Applicant of Cited Document	mm-dd-yyyy	passages or relevant figures appear	T ⁸
		PCT	98/33443	3				
	ļ							
	ļ							
	ļ							

Examiner	Date	
Signature	Considered	

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (VIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it displays a valid OMB control number.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCI.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 3 of 4

a conection of information unless it displays a	Valla Civid Control Hamber.
Application Number	10/805,736
Filing Date	March 22, 2004
First Named Inventor	Robert Falotico
Group Art Unit	3763
Examiner Name	
Attorney Docket Number	CRD5071USANP

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item	T²
Examiner's Initials*	Cite No.1	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	•
IIIIIais	110.	CLOWES, A.W and KARNOVSKY M., Nature 265:25-26, 1977	
		GUYTON, J.R. ET AL., Circ. Res., 46:625-634, 1980	
		CLOWES, A.W. AND CLOWES, M.M., Lab. Invest. <u>52</u> :611-616, 1985	
		CLOWES, A.W. AND CLOWES, M.M., Circ. Res. <u>58</u> :839-845, 1986	
		MAJESKY ET AL., Circ. Res. 61:296-300, 1987	
		SNOW ET AL., Am. J. Pathol. <u>137</u> :313-330, 1990	
		OKADA T. ET AL., Neurosurgery <u>25</u> : 92-98, 1989	
		CURRIER, J.W. ET AL., Circ. <u>80</u> :11-66, 1989	
		SOLLOT, S.J. ET AL., J. Clin. Invest. <u>95</u> : 1869-1876, 1995	
,		POWELL, J. S. ET AL., Science, 245: 186-188, 1989	
		LUNDERGAN, C. F. ET AL., Am J. Cardio. 17 (Suppl. B): 132B-136B, 1991	
		JONASSON, I. ET AL., Proc. Natl., Acad. Sci., 85: 2303, 1988	
		FERNS, G.A.A., ET AL., Science <u>253</u> : 1129-1132, 1991	
		NEMECEK, G.M. ET AL., J. Pharmacol Exp.Thera. 248: 1167-1174, 1989	
		LIU, M.W. ET AL., Circ. 81: 1089-1093, 1990	
		FUKUYAMA, J. ET AL., Eur. J. Pharmacol. <u>318</u> : 327-332, 1996	
		HANSSON, G.K. AND HOLM, J. Circ. 84: 1266-1272, 1991	
		MARX, S.O. ET AL., Circ. Res. <u>76</u> : 412-417, 1995	
		COLBURN, M.D. ET AL., J. VASC. SURG. <u>15</u> : 510-518, 1992	
		BERK, B.C. ET AL., J. Am. Coll. Cardiol. <u>17</u> : 111B-117B, 1991	
		WEINBERGER, J. ET AL., Int. J. Rad. Onc. Biol. Phys. <u>36</u> : 767-775, 1996	
		FARB, A. ET AL., Circ. Res. <u>80</u> :542-550, 1997	
		SIMONS, M. ET AL., Nature <u>359</u> : 67-70, 1992	
		CHANG, M.W. ET AL., J. Clin. Invest. <u>96</u> : 2260-2268, 1995	
		MODERN FLUOROPOLYMERS, (J Shires ed.), John Wiley & Sons, New York,	
		1997, pp. 77-87	
		AJROLDI, ET AL., Fluoroelastomers-dependence of relaxation Phenomena on	
		Compositions, Polymer 30, 2180, 1989	
		HANSON & HARKER, Proc. Natl. Acad. Sci. USA 85:3184-3188, 1988	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE o a collection of information unless it displays a valid OMB control number.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERC Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 4 of 4

Application Number	10/805,736
Filing Date	March 22, 2004
First Named Inventor	Robert Falotico
Group Art Unit	3763
Examiner Name	
Attorney Docket Number	CRD5071USANP

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		WOO ET AL., J. Med Chem, <u>45</u> :2877-2885, 2002	
		DEROANNE ET AL., Oncogene 21(3): 427-436, 2002	
		CARRERA ET AL., J. Clin. Invest. 86:1480-1488, 1990	
		CARSON ET AL., Blood 62:737-743, 1983	
		·	
	-		

Examiner	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.